

REMARKS

This paper is responsive to an Official Action that issued in this case on April 18, 2007. In that Action, the Examiner rejected pending claims 1-40 under 35 USC §102 as being anticipated by US Published Pat Application 2003/0031993 to Pugh.

Claim 1 has been amended to more particularly point out applicants' invention. Reconsideration is requested in view of the foregoing amendment and the following comments.

Background

The illustrative embodiment of applicants' claimed invention is a simulation system that provides realistic training and practice for performing vascular-access procedures without using human subjects. The simulation system is designed to more closely simulate a real vascular-access procedure than simulators in the prior art. A more realistic simulation is expected to result in a more useful training experience.

The illustrative vascular-access simulator includes a data-processing system and an interface device, referred to in the specification as a "haptics device." The haptics device provides the physical interface for performing vascular-access procedures. Some embodiments of the haptics device also provide mechanisms that enable a user to practice certain skin-interaction procedures (*i.e.*, palpation, occlusion and skin stretch).

In the Background section of applicants' disclosure (as well as in an Information Disclosure Statement), the applicants disclosed U.S. Pat. No. 6,470,302. That patent also discloses a vascular-access simulation system and is particularly relevant to applicants' simulation system. The present inventors recognized many shortcomings of the system that is disclosed in the '302 patent; shortcomings that they sought to avoid in development of their simulation system. Some of the shortcomings pertain to the ergonomics of the '302 system. And that is focus of the present application and claims.

More particularly, the various mechanisms within the claimed apparatus are configured so that one or more of the following conditions are met:

- The profile of the haptics device remains relatively low — advantageously not substantially higher than a person's arm when it is resting flat on a surface.

- The shape of the haptics device is not overtly inconsistent with human anatomy (*e.g.*, an arm, *etc.*).
- When practicing a vascular-access procedure using the haptics device, the position of a user's hands is similar to the position of the hands when performing an actual vascular-access procedure.
- The sites at which the palpation and skin stretch techniques are performed are correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
- The sites at which the occlusion and skin stretch techniques are performed are correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
- The sites at which the occlusion and skin stretch techniques are performed are correct relative to the site at which the catheter/needle is inserted into the haptics device (in terms of the sites of these techniques during an actual vascular-access procedure).
- The various mechanisms of the haptics device are beneath the "skin" of the haptics device.

The cited art, Pugh, is not relevant to the claimed invention. The purpose and physical configuration of the Pugh device is vastly different than applicants' device. As a consequence, few if any of the concerns that arise when developing a vascular-access simulation system are implicated with the manikin that disclosed by Pugh.

Of course, the key question is: does Pugh read on applicants' claims? The Office thinks so; applicants disagree for the following reasons.

**Pending Claims 1-40
Are Allowable over Pugh**

Amended claim 1 recites an apparatus comprising:

pseudo skin;
a receiver, wherein said receiver receives an end effector; and
a first device for performing a first skin-interaction technique
that is used in conjunction with a simulated vascular-access
procedure,
wherein said receiver and said first device are disposed beneath
said pseudo skin.

Claim 1 recites "a receiver" that "receives an end effector." In support of the rejection of claim 1, the Office points to the para. 0012 of Pugh wherein it is disclosed that the manikin can be used for "exams requiring palpation or manual assessment of body or anatomical surfaces." The Office alleges that an "end effector could comprise a user's hand." The Office's position is incorrect as far as a reasonable interpretation of applicants' claim language is concerned.

The term "end effector" was explicitly defined in applicants' specification at para. 0025 to mean "a device, tool, or instrument." Applicants' explicit definition also acknowledges that the term end effector is borrowed from robotics, wherein it has a somewhat different definition; namely "a device or tool connected to the end of a robot arm."

In either case, a human hand is not consistent with applicants' definition of an end effector as "a device, tool, or instrument." A hand can use "a device, tool, or instrument," but is not properly characterized as such.

As a consequence, it is not appropriate to construe the phrase "end effector" to encompass a "hand."

Furthermore, amended claim 1 recites "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." Pugh does not disclose such a device.

Vascular-access procedures are procedures that involve the insertion of a needle, catheter, *etc.* into the vascular system. Inserting an IV is a typical example of a "vascular-access procedure." There is no disclosure of performing procedures pertaining to the vascular system in Pugh's specification. Pugh references surgical and examination procedures pertaining to many different anatomical structures in his disclosure: breasts, spleen, liver, intestines, prostate, trachea, esophagus, and so forth. But there is no mention of performing vascular access procedures.

In conjunction with its remarks concerning claim 25, the Office alleges that "Pugh discloses that any type of surgical procedure ... may be taught with the invention." It is notable that the vascular-access procedures to which the claimed invention is addressed are not "surgical procedures." But in any case, it is quite clear that vascular-access procedures cannot be taught using Pugh's manikin.

As should be quite clear from applicant's disclosure, and the disclosure of the '302 patent as well, the configuration of a simulation system that is suitable for teaching vascular access procedures is very different than Pugh's manikin. Therefore, it cannot be said that there would be any suggestion or motivation to include, in Pugh's manikin, a "device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." Simply put, the technologies are quite different.

Claim 25 recites an apparatus comprising:

a housing;
an **end effector**, wherein said end effector is inserted into said housing during the performance of a **simulated vascular-access procedure**; and
a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing, and wherein said plurality of mechanisms include:
a first mechanism is for simulating a first skin-interaction technique; and
a second mechanism for receiving said end effector.

Applicants proffer the same points with respect to claim 25 as were raised for claim 1. That is, there is no disclosure to insert an end effector (as defined by applicants) into a housing during the performance of a simulated vascular-access procedure.

Claim 35 recites an apparatus comprising:

a pseudo skin;
a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, wherein said plurality of mechanisms are disposed under said skin; and
a housing, wherein said housing contains said plurality of mechanisms.

There is no disclosure in Pugh of any "vascular-access procedures" nor mechanisms with which a user interacts to simulate such procedures. The Office alleges otherwise, and cites to FIGs. 8, 14A-C, 15, 16 and paragraph [0062] as support.

FIG. 8 depicts "a portable training system **98**" with a simulator **100** that has sensors that are connected with a display screen **102**. The thin lines that interconnect the screen **102** with the simulator **100** are electrical interconnects (*e.g.*, wires, *etc.*) to conduct the signals from the sensors to the display screen. The Office seemingly confused the electrical interconnects with veins.

FIGs. 14A-C depict various surgical procedures. FIG. 14A depicts palpation of a colonic tumor, FIG. 14B depicts palpation of a pancreatic mass while preparing for a biopsy, and FIG. 14C depicts palpation of a neurogenic tumor arising in the abdominal wall. It is notable that a biopsy of a pancreatic mass is not a "vascular access procedure."

FIG. 15 illustrates a procedure wherein one hand of a surgeon is inserted through the diaphragm and the other is inserted through a cervical incision in the neck to perform a transhiatal esophagectomy. FIG. 16 illustrates a procedure for removing an intramural esophageal tumor.

None of these Figures present anything related to vascular access procedures.

Paragraph 0062 notes that many surgical procedures that have a component that must be performed manually on or inside an anatomical space and involving an organ or body surface can be taught using the invention. Perhaps so, but that doesn't include vascular access procedures, which are not mentioned by Pugh.

Conclusion

For the foregoing reasons, independent claims 1, 25, and 35 are believed to be allowable over the cited art. All dependent claims are allowable based on their dependence upon these allowable base claims. And the recitation of additional patentable features in the dependent claims provides a secondary basis for their patentability. As a consequence, a Notice of Allowance is solicited.

Respectfully,
David Feygin et al.

By **/Wayne S. Breyer/**
Wayne S. Breyer
Reg. No. 38089
Attorney for Applicants
732-578-0103 x12

DeMont & Breyer, L.L.C.
Suite 250
100 Commons Way
Holmdel, NJ 07733
United States of America